



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Prospective Grant of Exclusive Patent Commercialization License: Streptococcus
Pneumonia PSAA Peptide for Treatment of Sepsis and Infection**

AGENCY: National Institutes of Health, Department of Health and Human Services,
and Centers for Disease Control and Prevention.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, on behalf of the Centers for Disease Control and Prevention, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to The University of Liverpool, located in Liverpool, UK, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent commercialization license should be directed to: Karen Surabian, Licensing and Patenting Manager, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 301-496-2644, or karen.surabian@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement: United States Provisional Patent Application Number 61/085,208, filed 07/31/2008, entitled “Methods of Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-US-01); PCT Patent Application Number PCT/US2009/052384, filed 07/31/2009, entitled “Methods of Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-PCT-02); China Patent Number 200980137625.X, issued 11/26/2014, entitled “Methods of Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-CN-03); European Patent Number 2323684, issued 05/21/2014, entitled “Use of a Pneumococcal P4 Peptide for Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-EP-04), and validated in Germany, Spain, France, the United Kingdom, and Ireland; Hong Kong Patent Number 1160391, issued 07/31/2015, entitled “Methods of Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-HK-05); United States Patent Number 8,431,134, issued 04/30/2013, entitled “Use of a

Pneumococcal P4 Peptide for Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-US-06); United States Patent Number 9,101,582, issued 08/11/2015, entitled “Use of a Pneumococcal P4 Peptide for Enhancing Opsonophagocytosis in Response to a Pathogen” (HHS Reference No. E-329-2013/0-US-07); United States Provisional Patent Application Number 60/682,495, filed 05/19/2005, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-US-01); PCT Patent Application Number PCT/US2005/027290, filed 07/29/2005, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-PCT-02); Australia Patent Number 2005332058, issued 03/15/2012, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-AU-03); European Patent Number 1931700, issued 07/17/2003, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-EP-04), and validated in: Germany, Spain, France, the United Kingdom, and and Ireland; Hong Kong Patent Number 1115144, issued 02/14/2014, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-HK-05); United States Patent Number 7,919,104, issued 04/05/2011, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-US-06); Canada Patent Application Number 2,631,556, filed 09/15/2014, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-CA-07); Australia Patent Number 2012201107, issued 06/06/2013, entitled “Functional Epitopes of Streptococcus

Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-AU-08); Hong Kong Patent Number HK1163113, issued 06/05/2015, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-HK-09); European Patent Number 2371843, issued 09/17/2014, entitled “Functional Epitopes of Streptococcus Pneumonia PSAA Antigen and Uses Thereof” (HHS Reference No. E-338-2013/0-EP-10), and validated in: Germany, France, and the United Kingdom.

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide and the field of use may be limited to: “Development, manufacture, and sale of a P4 peptide therapeutic for the treatment of infection and sepsis.”

These inventions, developed within the National Center for Immunization and Respiratory Diseases (NCIRD), at the Centers for Disease Control and Prevention (CDC), describe methods to bolster the human body's own mechanisms to fight infection by enhancing an innate immune response, opsonophagocytosis. The specific 24 amino acid peptide sequence (P4) acts as a polymorphonuclear cell activator. P4 can be administered in vivo along with disease-specific antibodies to enhance systemic bacterial clearance, thus leading to prolonged survival. This technology enhances the body's response to a variety of bacterial infections, including *S. pneumoniae* and *S. aureus*.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent commercialization license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the

National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: June 11, 2018.

Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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